DETAILED ACTION

1. Applicant's response received November 20, 2007 is acknowledged.

Claims 44-54 are pending in the instant application.

The Notice of an Informal or Non-Responsive Amendment mailed 9/11/08 has been withdrawn in view the interview between the examiner and Ari Zytcer which took place on September 30, 2008, in which it was agreed that the response received November 20, 2007 was indeed fully responsive to the restriction requirement mailed September 28, 2007 and that a first action on the merits would follow soon thereafter.

Applicant's election without traverse of the species "chemical compound" as the agent that modulates transmission of immunity from mother to offspring via milk in the reply filed on November 20, 2007 is acknowledged.

Information Disclosure Statement

2. The IDS received 11/23/05 is acknowledged and has been considered.

Specification

3. The title of the application is objected to for not being specific for the instant claimed invention. Specifically, the title in no way indicates transmission of immunity via milk from mother to child is what is being investigated even though the claims clearly reflect this limited scope rather than generic screening methods for modulators of immunity in general as the instant title would suggest. Appropriate amendment of the title to better reflect that which is instantly claimed is suggested.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 48, 52 and 53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims recite "T-25-Adh cells" and "Rev-2-T-6 cells" as such these materials are required elements needed to make and use the claimed invention. As a required element, these cell lines must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the pertinent cell line. See 37 CFR 1.801-1.809.

The specification does not appear to disclose that the recited cell lines have been deposited under the terms of the Budapest treaty, the terms under which such a deposit may have been made, provide assurances that the recited materials will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, or indicate that said material will be replaced if the material becomes unviable.

If the deposit has been made under the terms of the Budapest Treaty, an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that "T-25-Adh cells" and "Rev-2-T-6 cells" have been deposited under the Budapest Treaty and that "T-25-Adh cells" and "Rev-2-T-6 cells" will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. See 37 CFR 1.808. Further, the record must be clear that the deposit will be maintained in a public depository for a period of 30 years after the date of deposit or 5 years after the last request for a sample or for the enforceable life of the patent, whichever is longer. See 37 CFR 1.806 and MPEP 2410-2410.01. If the deposit has not been made under the

Budapest treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature must be made, stating that the deposit has been made at an acceptable depository and that the criteria set forth in 37 CFR 1.801-1.809, have been met.

If the deposit was made after the effective filing date of the application for a patent in the United States, a verified statement is required from a person in a position to corroborate that the vector described in the specification as filed are the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 48, 52 and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite due to the recitation of "T-25-Adh cells" and "Rev-2-T-6 cells" as the sole means of identifying the material required to perform the claimed method since "T-25-Adh cells" and "Rev-2-T-6 cells" are merely laboratory designations that do not clearly define a particular cell in that artisans could use the same designations to define completely distinct biological materials, or in the alternative, could use different designations to define the exact same cells.

One possible means of obviating this rejection is to amend the claims to recite an accession number for a deposited of a cell line of the recited name, assuming that such a deposit can be made which satisfies the requirements of 37 CFR 1.801-1.809.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 44, 45, and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Coste et al. (reference A12 on the 11/23/05 IDS).

Coste et al. disclose methods wherein they studied how adjuvant influences the transfer of immunity via milk from vaccinated mothers to offspring (see entire document, particularly the abstract). Briefly, mothers were vaccinated against rotavirus, an antigen which is responsible for causing diarrhea disease in newborns, either with or without adjuvant, and were allowed too suckle their offspring. All the newborns were challenged with rotavirus, and a comparison was made between newborns receiving milk from mother that were immunized with adjuvant and newborns receiving milk from mother that were immunized without adjuvant. Note that the adjuvant used by Coste et al. was cholera toxin. Cholera toxin is a protein complex, and given that polypeptides are non-random arrangements of atoms including carbon, nitrogen, oxygen and hydrogen in a particular spatial order, polypeptides are "chemical compounds".

Therefore, the prior art anticipates the claimed invention.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 44-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coste et al. (reference A12 on the 11/23/05 IDS) in view of Hochman et al. (of record as reference A5 on the 11/23/05 IDS).

The disclosure of Coste et al. has been discussed above and differs from the instant claimed invention in that the antigen used in their methods was not a lymphoma cell line.

Hochman et al. disclose that mothers vaccinated with the T-25-Adh are able to make antibodies that are transferred to pups via milk that protect said pups from cancer when challenged with the Rev-2-T-6 lymphoma (see entire document).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to use cancerous cell lines in the methods of Coste et al. Motivation to do so comes from the fact that resistance to lymphoma can be transferred via antibodies from a vaccinated mother to naive children as documented by Hochman et al. and from the disclosure that Coste et al. that adjuvants are useful in increasing the immune response to antigens (see entire document, particularly page 8969). Thus, a person of ordinary skill in the art would perform the methods of Coste et al. using the antigens of Hochman et al. to try and increase the efficacy of the transfer of immunity between mothers and children that was seen in the results of Hochman et al.

12. No claims are allowable.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is (571)272-2934. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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